



PTO/SB/21 (07-06)

Approved for use through 09/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

32

Application Number

10/670,046

Filing Date

September 24, 2003

First Named Inventor

Frank Hardt

Art Unit

1771

Examiner Name

Daniel R. Zirker

Attorney Docket Number

R00233US.CON (#90568)

ENCLOSURES (Check all that apply)

Fee Transmittal Form



Fee Attached



Amendment/Reply



After Final



Affidavits/declaration(s)



Extension of Time Request



Express Abandonment Request



Information Disclosure Statement



Certified Copy of Priority Document(s)



Reply to Missing Parts/ Incomplete Application



Reply to Missing Parts under 37 CFR 1.52 or 1.53



Drawing(s)



Licensing-related Papers



Petition



Petition to Convert to a Provisional Application



Power of Attorney, Revocation



Change of Correspondence Address



Terminal Disclaimer



Request for Refund



CD, Number of CD(s) _____

☐ Landscape Table on CD

After Allowance Communication to TC



Appeal Communication to Board of Appeals and Interferences



Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)



Proprietary Information



Status Letter



Other Enclosure(s) (please identify below):

return postcard receipt

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name

D. Peter Hochberg Co., L.P.A.

Signature

Printed name

D. Peter Hochberg

Date

September 11, 2006

Reg. No.

24,603

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature

Typed or printed name

Sean F. Mellino

Date

09/11/2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Best Available Copy

SEP 14 2006

PTO/SB/17 (07-06)

Approved for use through 01/31/2007. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

Effective on 12/08/2004.

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2005☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 0.00

Complete if Known

Application Number	10/670,046
Filing Date	September 24, 2003
First Named Inventor	Frank Hardt
Examiner Name	Daniel R. Zirker
Art Unit	1771
Attorney Docket No.	RO0233US.CON (#90568)

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☒ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 08-2441 Deposit Account Name: D. Peter Hochberg Co., L.P.A.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims **Extra Claims** **Fee (\$)** **Fee Paid (\$)**

_____ - 20 or HP = _____ x _____ = _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims **Extra Claims** **Fee (\$)** **Fee Paid (\$)**

_____ - 3 or HP = _____ x _____ = _____

HP = highest number of independent claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).


Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
_____ - 100 = _____	_____ / 50 = _____	(round up to a whole number) x	250.00	0.00

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

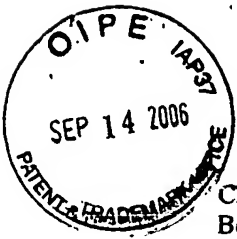
Other (e.g., late filing surcharge): _____

Fees Paid (\$)**SUBMITTED BY**

Signature		Registration No. (Attorney/Agent)	24,603	Telephone	216-771-3800
Name (Print/Type)	D. Peter Hochberg			Date	September 11, 2006

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



CERTIFICATE OF MAILING

I hereby certify that this document is being deposited with the United States Postal Service as First Class mail in an envelope addressed: Mail Stop Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia, 22313-1450, on the date noted below:

September 11, 2006
Date

Sean F. Mellino
Sean F. Mellino

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Frank Hardt & Paul Genich
Serial No. : 10/670,046 / Conf. No. 5022
Filing Date : September 24, 2003
Examiner / Group Art Unit : Daniel R. Zirker / 1771
Title : Method for Producing Adhesive Blanks From and
Endless Band and Blanks Obtained According to
Said Method
Attorney File : RO0233US.CON (#90568)
Technology Center : 1700
Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPEAL BRIEF (revised)

Dear Sir:

This brief is in furtherance of the Notice of Appeal submitted in this case on March 31, 2006 and received by the United States Patent and Trademark Office on April 3, 2006.

Enclosed is a Credit Card Payment Form authorizing a large entity charge of \$500.00 to cover the fee for filing the brief in support of the appeal. Please charge any additional fees which may be required for this matter to Applicant's attorney's Deposit Account No. 08-2441 – D. Peter Hochberg Co., L.P.A.

Real Party in Interest:

The real party in interest is the assignee of the Applicant, LTS Lohmann Therapie-Systeme AG.

Related Appeals and Interferences:

None.

Status of Claims:

Claims 1-8 are pending in the application. Claim 9 has been canceled. The rejection of claims 1-8 is being appealed.

Status of Amendments:

No further amendments have been filed subsequent to the Final Office Action which is dated November 8, 2005.

Summary of Claimed Subject Matter:

This invention relates to an adhesive die-cut article (page 3, line 22 (par. 0012); articles 11) having an external contour (page 4, line 5 (par. 0013); layer 5) which comprises an adhesive layer with an internal cut-out (page 4, line 5 (par. 0013; cut-out 3) also having a contour. The external contour has no common point with the contour of the internal cut-out (page 3, line 23 (par. 0012); cut-out 3). A matrix layer (page 3, line 18 (par. 0010); layer 6) is provided having an internal cut-out (page 8, line 2 (par. 0027); cut-out 3) which is congruent with the internal cut-out in the adhesive layer. The matrix layer is a compacted material. A covering film (page 4, line 3 (par. 0012); film 9) is provided for covering the composite of matrix layer, adhesive layer and internal cut-out and the internal cut-out is filled with a filler material (page 4, line 2 (par. 0012); material 2). The filler material contains a pharmaceutical active ingredient, such as salicylic acid, lactic acid, 5-fluoruracil, capsaicin, acetyl-salicylic acid, or nonoic acid vanillyl amide (page 8, lines 10-15 (par. 0029)). The adhesive article further includes a detachable protective film (page 7, line 19 (par. 0026); film 8). The filler material itself comprises a material such as a liquid, a semi-solid, gel-like, pasty, powdery and fusible materials, or a mixture thereof (page 8, lines 8-10 (par. 0029)).

The adhesive layer of the article of the present invention comprises a natural or synthetic polymer which may be, for example, polyacrylates, polyisobutylenes, silicones, rubber and SIS block copolymers (page 8, lines 16-20). The matrix layer of the adhesive die-cut article comprises a natural or synthetic polymer selected from the group consisting of polyacrylates, polyethylenes, polypropylenes, polybutylenes, polyurethanes, poly-1-butenes, polyisobutene, rubbers, silicone rubbers, cellulose, chemical pulp, paper,

cotton, acetylcellulose, celluloid, viscose, polyacrylonitrile, polyvinylalcohol, polyvinyl acetate, polyvinyl ether, and ethylene-vinyl acetate (EVA) copolymers (page 9, lines 1-11).

Grounds of Rejection to be Reviewed on Appeal:

The following issues are present in the present appeal:

1. Was the rejection of claims 1-8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention proper?
2. Was the rejection of claims 1-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement proper?
3. Was the rejection of claims under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,244,677 (Kreckel *et al.*) proper?

Argument:

The rejection of claims 1-8 under 35 U.S.C. 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention, the rejection of claims 1-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, and the rejection of claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,244,677 (Kreckel *et al.*) are improper and should be reversed.

Claim 1 recites an adhesive die-cut article having an external contour comprising an adhesive layer with an internal cut-out having a contour, wherein the external contour of the adhesive die-cut article has no common point with the contour of the internal cut-out. The adhesive die-cut article has a matrix layer having an internal cut-out which is congruent with the internal cut-out in the adhesive layer, and matrix layer is a compacted material. A covering film covers the composite of matrix layer, adhesive layer, and internal cut-out, and the internal cut-out is filled with a filler material containing a pharmaceutical active ingredient, which may be salicylic acid, lactic acid, 5-fluoruracil, capsaicin, acetyl-salicylic acid, and nonoic acid vanillyl amide.

The Examiner first states in the Final Office action dated November 8, 2005, on page 2, that claims 1-8 fail to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner, in particular, states that the language of claim 1 which reads “the matrix layer can be a compacted material” is vague, indefinite and confusing since the specification contains no suitable teaching as to just what constitutes a “compacted material.”

The Examiner next states in the Final Office action on page 3 that claims 1-8 are rejected as failing to comply with the enablement requirement in that the claims contain subject matter which was not described in the specification in such a way to enable one skilled in the art to make and/or use the invention. In particular, the Examiner argues that the specification provides no guidance as to what constitutes a “compacted material,” but that it only provides a discussion of the equivalence of a compacted material being a foam, fabric, porous sheet or non-woven fabric.

Lastly, the Examiner states in the Final Office action (on pages 3-4) that claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kreckel, et al. With reference to the initial Office action dated June 15, 2005, the Examiner argues that Kreckel, et al. teach a substantial anticipation of the claimed invention, disclosing an adhesive punchout article comprising an adhesive layer with an inner recess, the outer line of the adhesive punchout sharing no common point with the outline of the inner recess. The Examiner also states that the reference discloses an adhesive backed medicine pill die cut for application to the skin. The Examiner acknowledges that the reference fails to disclose the presence of any specific pharmaceutical active ingredients, such as those set forth in claim 1. However, the Examiner argues that the presence of almost any other pharmaceutical active ingredient would be an obvious modification to one of ordinary skill in the art, absent unexpected results. In the final Office action, the Examiner further argues that the specification either appears to give no meaningful guidance as to what a compacted material can be made from, or alternatively, claim 9 (now canceled) at least appeared to have formerly taught that it can be, e.g., a foam material. In the former instance, the Examiner states the reference teaches a “matrix

layer,” and in the latter instance, the Examiner states that the reference teaches a foamed material which it calls the carrier layer.

Rejection of claims 1-8 under 35 U.S.C. 112, second paragraph

The Applicants respectfully traverse the rejection on the basis that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter. The Applicants respectfully submit that, as set forth in M.P.E.P. Section 2173.02, the examiner’s focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. The Examiner should allow claims which define the patentable subject matter with a reasonable (emphasis provided) degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) the content of the particular application disclosure; (B) the teachings of the prior art; and (C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. (M.P.E.P. Section 2173.02, Ex. E). In particular, the Applicants respectfully submit that one having the ordinary level of skill in the art would readily recognize what a compacted material is.

The Applicants further respectfully submit that the term is a term of art which is in no way vague or confusing to one skilled in the art. The term “compact” is defined in

various dictionaries as “closely packed together, neatly fitted, joined firmly together, close, dense, solid, imporous, firm, compressed, pressed together or of firm texture.” See, for example, the Oxford Advanced Learner’s Dictionary of Current English (A.S. Hornby (Ed.) 3rd Edition 1974, Cornelsen & Oxford University Press) and found on the Internet at www.oup.com/oald-bin/web_getald7index1a.pl (Exhibit A) or the Merriam-Webster online Dictionary (www.m-w.com) (Exhibit B). Clearly, a compacted material is produced by the compression of material, which thus gets closely packed together, imporous and obtains a firm texture.

In addition to the above, the Applicants respectfully submit that the USPTO Patent Classification System (PCS) clearly defines what constitutes a “compact fiber article” in Class 28, Subclass 121. The PCS defines this as “a textile item that is formed by wrapping a mass of fibers within a covering and wherein the mass of fibers is compressed into a desired shape prior to, during or after the wrapping occurs” (Exhibit C). In addition, the USPTO classification system further defines “compacting” as “subjecting the contents material to forces which crowd portions of the contents into a more confined space or which contract or elongate the contents without breaking” (Class 53, Subclass 436) (Exhibit D). Still further, Class 100, Subclass 35+, concerns “presses,” i.e., apparatus for subjecting material to compressive force, including methods in which material is pressed to compact it to a smaller volume.

Based on the above, the Applicants respectfully submit that one skilled in the art of manufacturing dermal or transdermal drug application systems would readily recognize what a compact(ed) material is, regardless of whether the material is made of fibers, compressed foam or compressed particles, that the term is clear to one having the

ordinary level of skill in the art on its own and one skilled in the art would readily understand the meaning of the term “compacted” as it pertains to the relevant art.

Withdrawal of this rejection is respectfully requested.

Rejection of claims 1-8 under 35 U.S.C. 112, first paragraph

The Applicants respectfully traverse the rejection on the basis that the claims fail to comply with the enablement requirement as not having the subject matter described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. For the reasons set forth above, the Applicants respectfully reassert the position that one skilled in the art would readily recognize what a compacted material is. Moreover, the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchber*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984); M.P.E.P. Section 2164.05(b) (Exhibit F).

As noted in the final Office action, page 3, the Examiner states that canceled claim 9 taught that a compacted material could be selected from the group consisting of a foam, a fabric, a porous sheet or a non-woven fabric, but that the specification only discusses what a compacted material could be at paragraph 0031, which taught the equivalence (emphasis provided) of a compacted material, that being any of the remaining four embodiments set forth in the Markush group of canceled claim 9. The Applicants respectfully submit that such a conclusion appears to contradict the objection

that the claims fail to comply with the enablement requirement. Nevertheless, paragraph 0031 discloses that the matrix layer may be present as a compacted material, a foam, a fabric, a porous sheet or a non-woven fabric. It is not stated whether these different materials have different properties, serve different functions and/or each of those associated with certain advantages of the other one is not disclosed. Therefore, the Applicants respectfully disagree with the conclusion that these different materials for the matrix layer are intended to be equivalents. Each material may be used for the matrix layer; however, each material serves its own particular function and has its own particular attributes.

Even if the compacted material and the other materials for the matrix (i.e., foam, fabric, porous sheet, non-woven fabric) are equivalent from today's perspective, the Applicants respectfully submit that there is no evidence in the cited prior art or elsewhere in the record which would indicate that a compacted material could also be used for the matrix of the present invention. The Applicants respectfully submit that it is the merits of the inventors of the present invention who in fact identified the utility of using a compacted material for the matrix of die cut articles. The Applicants respectfully submit that it appears that the determination of the equivalence of a compacted material and the other aforementioned materials of the matrix layer is derived from an undue ex-post analysis, since the presumed equivalence was disclosed for the first time by the inventors in the specification of the present invention. It is the Applicants' position that particular features or embodiments of an invention can not and should not be held against the patentability of the invention. Therefore, the Applicants respectfully submit that the Examiner's note that paragraph [0031] teaches the equivalence of a compacted material

with any of the remaining four embodiments can not provide a ground for the present rejection. Withdrawal of this rejection is respectfully requested.

Rejection of claims 1-8 under 35 U.S.C. 103(a)

The Applicant respectfully traverses the rejection of claims 1-8 being obvious in light of the cited prior art. The Applicants first submit that pending claim 1 is directed to an adhesive die-cut article comprising a matrix layer being a compacted material which is provided with an internal cut-out which is filled with a filler material containing a pharmaceutical active ingredient selected from the group consisting of a salicylic acid, lactic acid, 5-fluoruracil, capsaicin, acetyl-salicylic acid, and nonoic acid vanillyl amide. The Applicants believe that a close inspection of the claimed pharmaceutical active ingredients reveals that the pharmaceutical active ingredients are not a merely arbitrary or random selection, but rather are pharmaceutical active ingredients which are used for topical treatment of certain skin disorders (e.g., spots, pimples, warts, calluses, corns, shingles). The lesions are restricted to particular small areas of the skin. Moreover, the treatment of the disorders is restricted to the area of the lesions in order to avoid inappropriate damage of any healthy skin adjacent to the affected site. This feature of the present invention is advantageous in particular because of the particularly aggressive nature of the listed pharmaceutical active ingredients.

Restricting access of the pharmaceutical active ingredient to the spot where action is desired cannot be achieved with a porous material, such as a foam, woven fabric, non-woven fabric or a porous sheet, because the pharmaceutical active ingredient can enter the pores and spaces of the porous material and, in turn, be spread across the area of the matrix layer. The pharmaceutical active ingredient could subsequently negatively affect

the adhesive properties of the adhesive layer which keeps the die-cut article attached to the patient's skin, might then disintegrate the adhesive layer and thereby obtain access to the healthy skin underneath the die-cut article.

On the other hand, the use of a compacted material for the matrix is beneficial in that the presence of the pharmaceutical active ingredient can be restricted to the internal cut-out of the die-cut article. The pharmaceutical active ingredient is unable to migrate through pores, which do not exist in a compacted material, to obtain access to the skin underneath the adhesive layer with which the matrix is provided. Although it is believed that these effects are impossible to quantify, the presently claimed adhesive die-cut is an article which demonstrates certain advantages.

Kreckel, et al. teach an adhesive punchout article wherein the matrix is a porous foam or non-woven fleece, rather than a compacted material. Kreckel, et al. do not teach the presence of any specific drug. Although any drug could presumably be incorporated into a device of Kreckel, et al., such teaching does not make the present invention obvious to one skilled in the art. Kreckel, et al. neither suggests the use of a compacted material nor addresses the problem that certain drugs will get in contact with the unaffected skin. Therefore, Kreckel, et al. does not provide a suggestion as to the specific drugs which are set forth in present claim 1. Moreover, Kreckel, et al. does not make the specific combination of a matrix made of a compacted material with a pharmaceutical active ingredient selected from the group consisting of salicylic acid, lactic acid, 5-fluoruracil, capsaicin, acetyl-salicylic acid, and nonoic acid vanillyl amide obvious to one skilled in the art at the time the present invention was made.

With regard to the Examiner's position that the specification does not provide a meaningful guidance as to what a compacted material is, the Applicants respectfully refer to the arguments set forth above regarding a compacted material being known to one skilled in the art. In summary, the meaning of a compacted material is well known in the art and therefore one skilled in the art would readily be aware of the meaning of the term. Consequently, the Applicants respectfully submit that an extensive description of a compacted material in the specification would not be necessary and was therefore omitted for the sake of brevity.

In particular reference to Kreckel, et al., the prior art does not indicate that a compacted material can be used as a matrix in die-cut articles. Beyond that, it can not be inferred from Kreckel, et al. that it might be advantageous to restrict topical application of certain drugs to the affected spots on the skin, and that this can be achieved by providing a die-cut article with an internal cut-out with a matrix which is made of a compacted material. Therefore, the Applicants submit that Kreckel, et al. does not render the present invention obvious at the time it was made.

In light of the aforementioned deficiencies of the teachings of Kreckel, et al., the Applicants respectfully submit that the reference fails to teach every limitation set forth in claims 1-8 and that due to these deficiencies. Withdrawal of this rejection is strongly requested.

SUMMARY

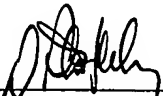
The Applicant respectfully submits that the cited references do not teach, suggest or show the present invention as presently claimed or advantages attendant thereto. In conclusion it is requested that the rejection of claims 1-8 as failing to comply with the

enablement requirement, as failing to particularly point out the intended invention and as being unpatentable over U.S. Patent No. 5,244,677 (Kreckel, *et al.*) under 35 U.S.C. §103(a) be withdrawn, that the Board reverse the decision of the Examiner and allow claims 1-8.

Date: September 11, 2006

D. Peter Hochberg Co., L.P.A.
The Baker Building – 6th Floor
1940 E. 6th Street
Cleveland, Ohio 44114
(216) 771-3800
Enc. Appendix

Respectfully submitted,

By: 
D. Peter Hochberg
Reg. No. 24,603

Claims Appendix

1. (previously presented) An adhesive die-cut article having an external contour comprising an adhesive layer with an internal cut-out having a contour, wherein the external contour of the adhesive die-cut article has no common point with the contour of the internal cut-out, a matrix layer having an internal cut-out which is congruent with the internal cut-out in the adhesive layer, said matrix layer being a compacted material, and a covering film covering the composite of matrix layer, adhesive layer, and internal cut-out, wherein the internal cut-out is filled with filler material containing a pharmaceutical active ingredient selected from the group consisting of salicylic acid, lactic acid, 5-fluoruracil, capsaicin, acetyl-salicylic acid, and nonoic acid vanillyl amide.
2. (previously presented) The adhesive die-cut article according to claim 1, further comprising a detachable protective film.
3. (previously presented) The adhesive die-cut article according to claim 1, wherein the internal cut-out has a circular shape.
4. (previously presented) The adhesive die-cut article according to claim 1, wherein the internal cut-out has a rectangular shape.
5. (previously presented) The adhesive die-cut article according to claim 1, wherein the thickness of the adhesive layer and of the matrix layer in sum are less than the maximum extent of the internal cut-out in longitudinal or transverse direction.
6. (previously presented) The adhesive die-cut article according to claim 1, wherein said filler material is selected from the group consisting of liquid, semi-solid, gel-like, pasty, powdery and fusible materials and mixtures thereof.
7. (previously presented) The adhesive die-cut article according to claim 1, wherein the adhesive layer comprises a natural or synthetic polymer selected from the group

consisting of polyacrylates, polyisobutylenes, silicones, rubber and SIS block copolymers.

8. (previously presented) The adhesive die-cut article according to claim 1, wherein the matrix layer comprises a natural or synthetic polymer selected from the group consisting of polyacrylates, polyethylenes, polypropylenes, polybutylenes, polyurethanes, poly-1-butenes, polyisobutene, rubbers, silicone rubbers, cellulose, chemical pulp, paper, cotton, acetylcellulose, celluloid, viscose, polyacrylonitrile, polyvinylalcohol, polyvinyl acetate, polyvinyl ether, and ethylene-vinyl acetate (EVA) copolymers.

9. (canceled)

Evidence Appendix

Exhibit A – Oxford University Press Online – Definition of “compact”

Exhibit B – Merriam-Webster Online Dictionary – Definition of “compact”

Exhibit C – USPTO Classification System Class 28, Subclass 121

Exhibit D – USPTO Classification System Class 53, Subclass 436

Exhibit E – Copy of relevant portion of MPEP 2173.02

Exhibit F – Copy of relevant portion of MPEP 2164.05(b)

BEST AVAILABLE COPY



English Language Teaching



•
•
•
•

New search:

Search

Select entry:

compact

compact *adj., noun, verb*

■ *adj.* /kəm'pækt; 'kɒmpækt; NAmE 'kɒm/

1 smaller than is usual for things of the same kind: *a compact camera* ❖ *The notebook computer is small and compact and weighs only 3.6lb.*

2 using or filling only a small amount of space: *The kitchen was compact but well equipped.*

3 closely and firmly packed together: *a compact mass of earth* ❖ *The grey clouds had become more compact and the sky suddenly grew dark.*

4 (of a person or an animal) small and strong: *He had a compact and muscular body.*

► *compactly* *adv.* *compactness* *noun* [U]: *He had the natural compactness of a good ball player.*

■ *noun* /kəm'pækt; NAmE 'kɒm/

1 (NAmE) a small car—compare SUBCOMPACT

2 a small flat box with a mirror, containing powder that women use on their faces

3 (formal) a formal agreement between two or more people or countries

■ *verb* /kəm'pækt/ [VN] [usually passive] to press sth together firmly: *a layer of compacted snow*

[Privacy Policy](#), [Cookie Policy](#) and [Legal Notice](#)

Copyright © Oxford University Press, 2005. All Rights Reserved.

EXHIBIT

A

BEST AVAILABLE COPY

Definition of compact - Merriam-Webster Online Dictionary - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Search Search Favorites

Links Address http://www.m-w.com/dictionary/compact

Merriam-Webster ONLINE Merriam-Webster COLLEGIATE Merriam-Webster UNABRIDGED

Ask.com search now Search

TOP TV SHOW SEARCHES

American Idol Family Guy South Park Pimp My Ride SpongeBob The Simpsons

HOME PREMIUM SERVICES M-W Collegiate.com M-W Unabridged.com Britannica.com Multi-User Licenses DOWNLOADS WORD OF THE DAY WORD GAMES SPELLING BEE HIVE WORD FOR THE WISE ONLINE STORE HELP Merriam-Webster Inc. Copyright © 2004

Merriam-Webster Online Dictionary

compact

One entry found for compact.

Main Entry: ² compact
transitive-senses
1 : to make up by connecting or combining : COMPOSE
2 a : to knit or draw together : COMBINE b : to press together : COMPRESS
intransitive senses : to become compacted
- com·pact·ible *adjective*
- com·pact·er also com·pact·er *noun*

For More Information on "compact" go to

Merriam-Webster Online
Dictionary
Thesaurus
Go

Browse by letter:
A B C D E F G H I J K L
M N O P Q R S T U V W X
Y Z

Browse words next to:
compact

compact Find

Weight Watchers

EXHIBIT

B

121 Compacted fiber article encasing:

This subclass is indented under **subclass 116**. Method or apparatus wherein a textile item is formed by wrapping a mass of fibers within a covering and wherein the mass of fibers is compressed into a desired shape prior to, during or after the wrapping occurs.

SEE OR SEARCH CLASS:

- 29,** Metal Working, appropriate subclass, for methods and apparatus making composite articles.
- 53,** Package Making, appropriate subclass, for the wrapping of articles in packaging material.

EXHIBIT

C

436 Compacting or stretching:

This subclass is indented under **subclass 428**. Methods including subjecting the contents material to forces which crowd portions of the contents into a more confined space or which contract or elongate the contents without breaking.

SEE OR SEARCH THIS CLASS, SUBCLASS:

523+, for corresponding apparatus.

SEE OR SEARCH CLASS:

100, Presses, subclasses **35+** for methods of compacting or compressing with presses.

EXHIBIT

D

The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.

2173.01 Claim Terminology [R-2]

A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as **>any special meaning assigned to a term is clearly set forth in the specification. See MPEP § 2111.01.< Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought.

2173.02 Clarity and Precision [R-1]

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, >by providing clear warning to others as to what constitutes infringement of the patent<. See, e.g., *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). See also *In re Larsen*, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished) (The preamble of the *Larsen* claim recited only a hanger and a loop but the body of the claim positively recited a linear member. The court observed that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. Upon review of the claim in its entirety, the court concluded that the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112 paragraph 2.).

>If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph, would be appropriate. See *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993). However, if the language used by applicant satisfies the statutory requirements of 35 U.S.C. 112, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used, the claim must not be rejected under 35 U.S.C. 112, second paragraph, rather, the examiner should suggest improved language to the applicant.

For example, a claim recites "a suitable liquid such as the filtrate of the contaminated liquid to be filtered and solids of a filtering agent such as perlite, cellulose powder, etc." The mere use of the phrase "such as" in the claim does not by itself render the claim indefinite. Office policy is not to employ *per se* rules to make technical rejections. Examples of claim language which have been held to be indefinite set forth in MPEP § 2173.05(d) are fact specific and should not be applied as *per se* rules. The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). If one skilled

BEST AVAILABLE COPY

EXHIBIT

E

BEST AVAILABLE COPY

the nature of the invention, the state of the prior art, and the level of skill in the art. The initial inquiry is into the nature of the invention, i.e., the subject matter to which the claimed invention pertains. The nature of the invention becomes the backdrop to determine the state of the art and the level of skill possessed by one skilled in the art.

The state of the prior art is what one skilled in the art would have known, at the time the application was filed, about the subject matter to which the claimed invention pertains. The relative skill of those in the art refers to the skill of those in the art in relation to the subject matter to which the claimed invention pertains at the time the application was filed. See MPEP § 2164.05(b).

The state of the prior art provides evidence for the degree of predictability in the art and is related to the amount of direction or guidance needed in the specification as filed to meet the enablement requirement. The state of the prior art is also related to the need for working examples in the specification.

The state of the art for a given technology is not static in time. It is entirely possible that a disclosure filed on January 2, 1990, would not have been enabled. However, if the same disclosure had been filed on January 2, 1996, it might have enabled the claims. Therefore, the state of the prior art must be evaluated for each application based on its filing date. 35 U.S.C. 112 requires the specification to be enabling only to a person "skilled in the art to which it pertains, or with which it is most nearly connected." In general, the pertinent art should be defined in terms of the problem to be solved rather than in terms of the technology area, industry, trade, etc. for which the invention is used.

The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004) ("a patent document cannot enable technology that arises after the date of application"). Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. *In re Gunn*, 537 F.2d 1123, 1128, 190 USPQ 402, 405-06 (CCPA 1976); *In re Budnick*, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976) (In

general, if an applicant seeks to use a patent to prove the state of the art for the purpose of the enablement requirement, the patent must have an issue date earlier than the effective filing date of the application.) While a later dated publication cannot supplement an insufficient disclosure in a prior dated application to make it enabling, applicant can offer the testimony of an expert based on the publication as evidence of the level of skill in the art at the time the application was filed. *Gould v. Quigg*, 822 F.2d 1074, 1077, 3 USPQ2d 1302, 1304 (Fed. Cir. 1987).

In general, the examiner should not use post-filing date references to demonstrate that the patent is nonenabling. Exceptions to this rule could occur if a later-dated reference provides evidence of what one skilled in the art would have known on or before the effective filing date of the patent application. *In re Hogan*, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977). If individuals of skill in the art state that a particular invention is not possible years after the filing date, that would be evidence that the disclosed invention was not possible at the time of filing and should be considered. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513-14 (Fed. Cir. 1993) an article published 5 years after the filing date of the application adequately supported the examiner's position that the physiological activity of certain viruses was sufficiently unpredictable so that a person skilled in the art would not have believed that the success with one virus and one animal could be extrapolated successfully to all viruses with all living organisms. Claims not directed to the specific virus and the specific animal were held nonenabled.

2164.05(b) Specification Must Be Enabling to Persons Skilled in the Art

The relative skill of those in the art refers to the skill of those in the art in relation to the subject matter to which the claimed invention pertains at the time the application was filed. Where different arts are involved in the invention, the specification is enabling if it enables persons skilled in each art to carry out the aspect of the invention applicable to their specialty. *In re Naquin*, 398 F.2d 863, 866, 158 USPQ 317, 319 (CCPA 1968).

When an invention, in its different aspects, involves distinct arts, the specification is enabling if it enables those skilled in each art, to carry out the aspect proper to their specialty. "If two distinct technologies are relevant to an invention, then the disclosure will be adequate if a person of ordinary skill in each of the two technologies could practice the invention from the disclosures." *Technicon Instruments Corp. v. Alpkem Corp.*, 664 F. Supp. 1558, 1578, 2 USPQ2d 1729, 1742 (D. Ore. 1986), aff'd in part, vacated in part, rev'd in part, 837 F.2d 1097 (Fed. Cir. 1987) (unpublished opinion), appeal after remand, 866 F.2d 417, 9 USPQ2d 1540 (Fed. Cir. 1989). In *Ex parte Zechnall*, 194 USPQ 461

EXHIBIT

F

Related Proceedings Appendix

None.